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(11) **EP 1 602 336 A2**

(12) **EUROPEAN PATENT APPLICATION**

(43) Date of publication:
07.12.2005 Bulletin 2005/49

(51) Int Cl.7: **A61B 17/34**

(21) Application number: **05253370.0**

(22) Date of filing: **01.06.2005**

(84) Designated Contracting States:
**AT BE BG CH CY CZ DE DK EE ES FI FR GB GR
HU IE IS IT LI LT LU MC NL PL PT RO SE SI SK TR**
Designated Extension States:
AL BA HR LV MK YU

(30) Priority: **01.06.2004 US 575958 P
01.02.2005 US 648791 P**

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(54) **System and method for accessing a body cavity**

(57) A device and method for accessing the interior of a cavity of a patient is described. The transmural access system includes an overtube (110) for use with an endoscope, a safety trocar (500), suture anchors (115), and a suture exchanger (151). The overtube is deployed in conjunction with an endoscope through a selected body passageway of a patient to locate a sight for an access portal. The distal end of the multi-lumen overtube is secured to an interior body wall of the selected access portal. A safety trocar is advanced through the main lumen of the overtube to form the access portal to the body cavity. Upon completion of the desired medical procedure, the access portal can be closed by deploying a suture exchanger.

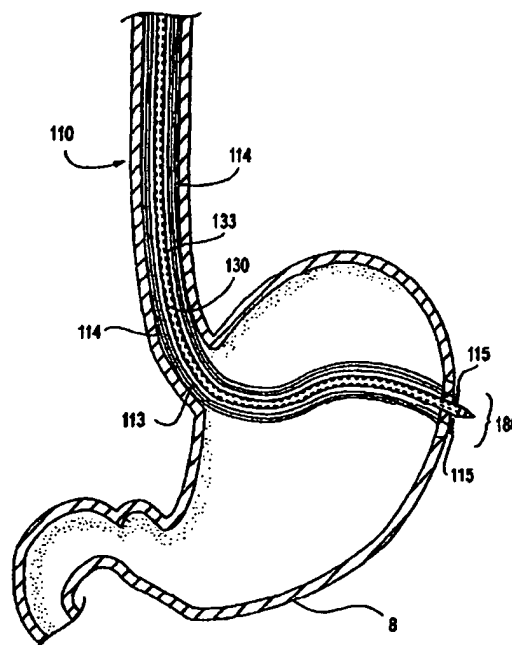


FIG. 15

Description

TECHNICAL FIELD

[0001] The invention generally relates to methods and devices for accessing a body cavity of a patient.

BACKGROUND

[0002] For some time, open surgery has been used to access a body cavity of a patient to examine or treat various diseases or injuries. Open surgery typically involves forming a transabdominal incision through the abdomen wall. This incision provides a physician with direct access to the peritoneal cavity and its organs. As generally illustrated in Figure 1, the peritoneum 1 includes a main cavity or greater sac 2, which contains the small intestine 6, transverse colon 7, stomach 8, liver 9, bare area of liver 10, pancreas 11, duodenum 12, aorta 13, and mesentery 14.

[0003] An alternative and somewhat less traumatic surgical technique used to access an internal cavity of a patient involves laparoscopy. During laparoscopy, a laparoscope and other surgical instruments are inserted through one or more small incisions of the anterior abdominal wall, e.g., a transumbilical incision. Patients undergoing laparoscopy generally have shorter recovery times and less incision pain than those using traditional open surgery.

[0004] However, open and laparoscopic surgery have numerous drawbacks. In the case of open surgery those drawbacks include relatively long and painful recovery periods, a heightened risk of infection, and large, aesthetically undesirable scars. In the case of laparoscopic procedures, there are other drawbacks. For example, laparoscopic techniques may be unsuitable for some patients, including pregnant women, and those with previous abdominal surgery. And, although not as severe as in open surgery, patients are left with aesthetically undesirable scars where incisions are made to access the abdomen.

SUMMARY

[0005] Accordingly, it is an object of the present invention to provide a medical device, system, and method that resolves or improves upon one or more of the above-described drawbacks.

[0006] In one aspect, the foregoing object is obtained by providing access to a body cavity, such as the peritoneal cavity, via the stomach or rectum. This is accomplished by a transmural access system. The transmural access system includes an overtube that is flexible and has a plurality of lumens. One of the lumens is configured to receive an endoscope. Additional lumens can be provided to pass an attachment mechanism, such as suture anchors, to the distal end of the overtube.

[0007] In a second aspect, the transmural access sys-

tem includes a trocar and sheath for forming and maintaining an access portal in a body wall. The trocar is configured to pass through one of the lumens of the overtube. The trocar and sheath preferably have an axial length between 50cm and 100cm. An alternative safety trocar is also disclosed. The safety trocar includes at its distal end an obturator tip. The obturator tip is slidable between a first position and a second position. In the first position the distal tip is located distally to the trocar tube distal end, and in the second position, the distal tip is located proximal to the trocar tube distal end. A dilator tip is operably connected to the distal end of the trocar tube.

[0008] In a third aspect, the transmural access system includes a suture exchanger for use with the overtube. The suture exchanger is configured to catch or secure suture anchors and withdraw the suture ends proximally through the overtube. The suture exchanger includes a shaft having a proximal end, a distal end, and a central portion therebetween. The central portion has an axial length between 30 centimeters and 120 centimeters and an outside diameter less than 3 centimeters. A hook or other tool is formed on the distal end of the shaft in order to catch or secure the sutures. The shaft can then be removed from the overtube, thereby withdrawing the distal ends of the sutures for knotting.

[0009] In a fourth aspect, a method is disclosed for transmurally accessing a body cavity of a patient. The method includes providing a multi-lumen overtube having a proximal end, a distal end, a main lumen and at least one attachment lumen. An endoscope is positioned to extend through at least a portion of the main lumen. At least one attachment mechanism is provided to extend through at least a portion of the at least one attachment lumen. The overtube can then be advanced through a body orifice into and along at least a portion of a body passageway such that the distal end is adjacent a selected portal sight along a body wall (e.g., the stomach). The distal end of the overtube is then secured to the body wall at the selected portal sight by advancing the at least one attachment mechanism through the at least one attachment lumen and into the body wall adjacent the selected portal sight. The endoscope can then be withdrawn from the main lumen, and a flexible trocar advanced therethrough. The flexible trocar is used to form a portal at the selected portal sight. Once a portal is formed, the endoscope can be readvanced through the main lumen so that a distal end of the endoscope is disposed adjacent or through the portal. This allows viewing at least a portion of the body cavity. After the desired examination or procedure is complete, the portal can be sutured by traditional techniques or with a suture anchor.

BRIEF DESCRIPTION OF THE DRAWINGS

[0010] Embodiments of the present invention will now be described by way of example with reference to the

accompanying drawings, in which:

[0011] Figure 1 is a partial, cross-sectional view of the peritoneum 1 that lines the wall of the abdominal cavity and folds inwards to enclose the viscera;

[0012] Figure 2 is cross-sectional view of a flexible, multi-lumen overtube according to an embodiment of the present invention;

[0013] Figure 3 is a sectional view of the overtube of Figure 2 taken along line 3-3;

[0014] Figure 4 is a view of a suture anchor according to an embodiment of the present invention;

[0015] Figure 5 is a side-view of a needle introducer according to an embodiment of the present invention;

[0016] Figure 6 is a cross-sectional view of needle introducers inserted into the overtube of Figure 2;

[0017] Figure 7 is a side-view of a pushing rod according to an embodiment of the present invention;

[0018] Figure 8 is a side-view showing the suture anchor pre-loaded within the needle introducer and the pushing rod ready to be introduced into the needle introducer;

[0019] Figure 9 is a side-view showing the pushing rod being advanced into the needle introducer and the suture anchor projecting through the needle introducer;

[0020] Figure 10 is a side-view of a flexible trocar according to an embodiment of the present invention;

[0021] Figure 11 is a side-view of a sheath according to an embodiment of the present invention;

[0022] Figure 12 is a side-view of the flexible trocar of Figure 9 positioned within the sheath of Figure 11;

[0023] Figure 13 is a partial, cross-sectional view showing the flexible, multi-lumen overtube of Figure 2 positioned in the mouth and along the esophagus of a patient such that the overtube distal end is positioned against a selected portal sight of the stomach wall;

[0024] Figure 14 is a partial, cross-sectional view illustrating the overtube distal end secured to the selected portal sight of the stomach wall with suture anchors and an endoscope positioned within the overtube;

[0025] Figure 15 is a partial, cross-sectional view showing the overtube distal end secured to the selected portal sight of the stomach wall with suture anchors and a sheathed flexible trocar puncturing the selected portal sight such that the sheath and the flexible trocar extend through the stomach wall;

[0026] Figure 16 is a view similar to Figure 15 showing the flexible trocar withdrawn from the sheath, the sheath remaining extended through the stomach wall and having an endoscope disposed therein;

[0027] Figure 17 is a perspective side view showing the overtube distal end partly separated from the stomach wall with suture anchors extending from the stomach wall into the attachment lumens of the overtube;

[0028] Figure 18 is a perspective side view showing the overtube distal end, suture anchors extending from the stomach wall into the attachment lumens of the overtube, and an exemplary suture exchanger engaging the suture anchors;

[0029] Figure 19 is a perspective side view showing the overtube distal end, suture anchors extending from the stomach wall into the attachment lumens of the overtube, and an exemplary suture exchanger retracting the suture anchors;

[0030] Figure 20 is a cross-sectional side view showing the exemplary suture exchanger withdrawing the suture anchors through the central lumen of the overtube;

[0031] Figure 21 is a perspective side view of a retractor for use with the overtube;

[0032] Figure 22 is a cross-sectional view showing the overtube;

[0033] Figure 23 is a cross-sectional view showing the overtube;

[0034] Figure 24 is a flow-chart showing a method of using a suture exchanger;

[0035] Figure 25 is a flow-chart showing a method of ligating a puncture site;

[0036] Figure 26 is a cross-sectional side view showing the flexible, long safety trocar in accordance with an embodiment of the present invention;

[0037] Figure 27 is a cross-sectional side view showing the obturator tip completely retracted within the dilator tip;

[0038] Figure 28 is an end view of the dilator tip showing the opening through which the obturator tip extends and retracts;

[0039] Figure 29 is cross-sectional side view of the safety trocar without the obturator inserted;

[0040] Figure 30 is a cross-sectional side view showing the obturator for use with the safety trocar;

[0041] Figure 31 is a perspective side view showing an exemplary knife edge;

[0042] Figure 32 is a perspective side view showing an exemplary knife edge;

[0043] Figure 33 is a perspective side view showing an exemplary knife edge;

[0044] Figure 34 is a cross-sectional side view of a trocar tube having proximal flanges and a spring-loaded obturator according to an embodiment of the present invention;

[0045] Figure 35 is a cross-sectional side view of the spring-loaded obturator within the trocar tube;

[0046] Figure 36 is a cross-sectional side view showing the spring-loaded obturator compressed by the flanged trocar tube with the obturator tip extending distally from the dilator tip according to an embodiment of the present invention;

[0047] Figure 37 is a cross-sectional side view showing a ratchet mechanism for extension and retraction of the obturator within the trocar tube according to an embodiment of the present invention; and

[0048] Figure 38 is a cross-sectional view of the safety trocar tube with the obturator withdrawn and the overlying outer protective sheath positioned within an overtube according to an embodiment of the present invention.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

[0049] Referring now to the Figures wherein like numerals indicate the same element throughout the views, there is shown in Figure 1 an abdominal cavity of a patient. More specifically, Figure 1 illustrates the peritoneum lining the walls of the abdominal cavity and folding inward to enclose the viscera. The peritoneum comprises a main cavity, or greater sac, 2 and the omental bursa, or lesser sac, 3, which are connected by the epiploic foramen 4. Numerous peritoneal folds extend between the various organs to hold the viscera in position.

[0050] A new paradigm to access the tissues and organs of a patient is to examine them with a flexible endoscope passed through a portal formed in a natural passageway of a patient. In one non-limiting example, such an approach is used to access the pancreas through the stomach wall. Using this approach, a flexible endoscope is passed into a patient's mouth through the esophagus, stomach, posterior stomach wall and into the lesser sac. This approach enables direct inspection of the pancreas for visual diagnosis, guided high-frequency ultrasound with a probe, targeted biopsy, or direct access for therapy. Although the invention is described with reference to peritoneal access through the esophagus and stomach wall, one of ordinary skill in the art would appreciate the peritoneal cavity may also be accessed through other body passageways such as the colon by way of a non-limiting example. Further, application of the principles of the invention to access other body cavities, such as the thoracic cavity by way of a non-limiting example, is also within the ordinary skill in the art.

[0051] Referring now to Figures 2-11 and 17-23, a transmural access system made in accordance with an embodiment of the present invention is shown. In general, the transluminal access system includes a flexible, multi-lumen overtube 110, an attachment mechanism 115, a flexible trocar 130, and a suture exchanger 140. The overtube is used in combination with an endoscope to establish a passageway to a target portal site in the stomach. The attachment mechanism, which includes one or more suture anchors, is used to attach the overtube to the stomach wall. Once the overtube is attached to the stomach wall, the flexible trocar is passed through the overtube, and is used to puncture the stomach wall, thereby creating access to the peritoneal cavity. Once a desired procedure in the peritoneal cavity is complete, the suture exchanger is used to retract the suture anchors, as described in greater detail below.

[0052] The flexible, multi-lumen overtube 110 comprises a distal end 111, a proximal end 112, a main lumen 113 and at least one attachment lumen 114. Any arrangement of the main lumen and the at least one attachment lumen is contemplated. Figures 2 and 3 illustrate one embodiment of the flexible, multi-lumen overtube having a main lumen 113 with four attachment lu-

mens 114 equally spaced about the main lumen 113. The flexible multi-lumen overtube 110 can have a single-piece construction as shown in the embodiment depicted in Figures 2 and 3. Alternatively, several tubes may be bonded together to form the flexible, multi-lumen overtube 110. The flexible, multi-lumen overtube 110 can be made from any suitable material known in the art including, but not limited to, polyethylene ether ketone (PEEK), polytetrafluoroethylene (PTFE), polyamide, polyurethane, polyethylene and nylon, including multi-layer or single layer structures and may also include reinforcement wires, braid wires, coils and or filaments. Optionally, the flexible, multi-lumen overtube 110 further comprises valve 199 over its proximal end 112. Valve 199 forms a seal between the flexible, multi-lumen overtube 110 and the endoscope or other device that is advanced therethrough to prevent the loss of any pressurized fluid that is introduced through the endoscope or other device, as will be explained in further detail below. In one embodiment, valve 199 is removable. One of ordinary skill in the art would know how to assemble valve 199 over the proximal end 112 of multi-lumen overtube 110.

[0053] The main lumen 113 is configured to receive and pass an endoscope 120, as shown in Figure 14, a flexible trocar 130, as shown in Figure 15, or an exchanger 151, as shown in Figures 18-20. The main lumen 113 ranges in size from about 4 mm to about 9 mm. These sizes are provided for illustrative purposes only and are not intended to be construed as a limitation of the present invention. As one of ordinary skill in the art would appreciate, since the endoscope 120 and the flexible trocar 130 are advanced through the main lumen 113, the size of the main lumen 113 is related to the size of either the endoscope 120 or the flexible trocar 130, whichever is larger. One of ordinary skill in the art would also appreciate that the size of the trocar is related to the size of the medical instruments that are passed therethrough for the diagnosis and treatment of the tissues and organs within the body cavity. Thus, a flexible, multi-lumen overtube having a main lumen smaller than about 4 mm used with endoscopes or trocars having an outer diameter smaller than about 4 mm that may become available in the future are contemplated as being within the scope of the claims of the present invention.

[0054] The attachment lumen 114 is configured to receive and pass an attachment mechanism 115 (see Figure 4). In one embodiment of the flexible, multi-lumen overtube 110, the at least one attachment lumen 114 and the main lumen 113 comprise a longitudinal slit (not shown) along its length so that the attachment mechanism 115 can be pulled from the at least one attachment lumen 114 into the main lumen 113 as explained more fully below.

[0055] With respect to the attachment mechanism 115 of the transmural access system of the present invention, any mechanism configured to be advanced through the attachment lumen, secure the overtube dis-

tal end 111 to a body wall, and ligate a portal in the body wall is contemplated. Figure 4 illustrates a non-limiting embodiment of an attachment mechanism comprising a suture anchor 115. One exemplary suture anchor 115 comprises a spring coil anchor 118 and a suture portion 119, such as the Cope suture anchor manufactured by Cook, Incorporated, Bloomington, IN.

[0056] As illustrated in Figure 21, the suture exchanger 151 generally comprises a shaft having proximal portion 153 and distal portion 155. The suture exchanger is sized to fit through the main lumen of the overtube 110. The suture exchanger will generally have a length between 50cm and 100cm. However, a suture exchanger having a shorter length, for example for pediatric applications, could alternatively be used. The suture exchanger can be formed from any number of materials that can impart axial rotation from the proximal portion to the distal portion of the shaft, while maintaining the flexibility necessary to pass through the central passageway of the overtube. For example, suture exchanger can be formed from stainless steel, a rigid plastic, or a superelastic alloy such as nickel-titanium.

[0057] As illustrated in Figure 21, proximal portion 153 of suture exchanger 151 includes a handle 159 that allows a physician to easily grip and control the suture exchanger. The distal portion 153 of suture exchanger 151 is adapted to catch, pull, loop, or ensnare the suture portion of the suture anchor(s) and then withdraw the suture portions through the main lumen, as described in greater detail below. In one embodiment, the distal portion 155 includes sickle-shaped hook 157 that is offset from the longitudinal axis A formed by the shaft. Of course, other alternatively-shaped distal portions will become apparent to one of ordinary skill in the art in view of the present disclosure.

[0058] The transmural access system of the present invention is used to examine or treat tissues or organs within a body cavity, e.g. the peritoneal cavity, as follows. An endoscope 120 is disposed within the main lumen 113 of the flexible, multi-lumen overtube 110 (see Figure 14). The flexible, multi-lumen overtube and endoscope are inserted within a body orifice of a patient. Any body orifice is contemplated including, but not limited to, the mouth or anus. The flexible, multi-lumen overtube and endoscope are advanced through a body passageway and a sight for an access portal along a body wall is selected endoscopically. For example, if access to the peritoneal cavity is sought through the mouth, esophagus and stomach, a sight for the gastric portal through the posterior stomach wall is selected as shown in Figure 13. Alternatively, if access to the peritoneal cavity is sought through the anus, rectum and colon, a sight for an access portal through an intestinal wall is selected.

[0059] Next, the body cavity is insufflated to provide an unobstructed view of the tissues and organs therein, to protect the tissues and organs from damage as the access portal is formed and to provide a working space

within the cavity. With respect to accessing the peritoneal cavity, for example, an insufflation needle (not shown) is deployed through the endoscope and punctures the stomach wall. A suitable gas, such as carbon dioxide, is injected through the endoscope to expand the peritoneal cavity. Valve 199 at the overtube proximal end prevents the gas from escaping about the endoscope.

[0060] Optionally, a wire guide is placed through the insufflation needle to maintain access to the puncture site.

[0061] After insufflation of the body cavity, the insufflation needle is removed and the overtube distal end 111 is secured to the stomach wall. In one embodiment, shown in Figures 2-4 and 14-16, at least one suture anchor 115 is passed through the at least one attachment lumen 114 and deployed into the selected portal site of the body wall 180.

[0062] Figures 4-8 illustrate a non-limiting, exemplary method pre-loading and deploying the suture anchor 115 through the attachment lumen 114 of the flexible, multi-lumen overtube 110. A suture anchor 115 (shown in Figure 4) is inserted into a needle introducer 160 (shown in Figure 5). Once the suture anchor 115 is pre-loaded into the needle introducer 160, the needle introducer 160 is passed through the attachment lumen 114 of the flexible, multi-lumen overtube 110 (shown in Figure 6) and the suture needle 160 is inserted through the stomach wall at the selected access portal sight. To deploy the suture anchor 115 through the attachment lumen 114, a pusher rod 170 (Figure 7) is used to push the suture anchor 115 so that the spring coil 118 is advanced through the needle lumen 160 as shown in Figures 8 and 9. Once the suture anchor 115 is deployed, the needle introducer 160 is removed from the attachment lumen 114.

[0063] The overtube distal end 111 can be positioned firmly against the body wall by proximally pulling the suture portion 119 of the suture anchor 115. The proximal end suture portion 119 can be held by the physician or secured to the proximal end 112 of the flexible, multi-lumen overtube 110.

[0064] As shown in Figure 14, since the endoscope 120 remains within the main lumen 113 of the flexible, multi-lumen overtube 110, a physician can view the deployment of the suture anchor 115 through the body wall at the selected access portal sight 180. This affords the physician the ability to attach the overtube distal end 111 against a body wall such that the main lumen 113 is precisely aligned with the selected access portal sight 180.

[0065] Once the distal end 111 of the flexible, multi-lumen overtube 110 is secured to the selected portal sight 180, the endoscope 120 is removed and a trocar 130 is advanced through the main lumen 113 of the flexible, multi-lumen overtube 110 and into the body wall to form the access portal to the body cavity as shown in Figure 15 and as described above. If a wire guide has been placed and the trocar 130 comprises a wire guide

lumen 137, then the trocar 130 is advanced over the wire guide.

[0066] Since the suture anchor 115 retains the over-tube distal end 111 against the body wall at the selected portal sight 180, the overtube distal end 111 cannot shift as the physician forms the access portal through the body wall. This facilitates the formation of the access portal by providing a controlled puncture of the body wall and enables the physician to accurately locate the access portal at the selected portal sight 180. Moreover, since the overtube distal end 111 is secured against the interior body wall at the selected portal sight 180, the flexible, multi-lumen overtube 110 cannot extend or pass through the access portal. This eliminates any potential damage caused to tissues and organs within the body cavity due to over insertion of the flexible, multi-lumen overtube.

[0067] Once the access portal to the body cavity is formed, the trocar 130 is withdrawn. An endoscope or other instrumentation can be inserted through the main lumen 113 of the flexible, multi-lumen overtube 110 for examination, diagnosis and/or treatment of the tissues or organs within the body cavity. Alternatively, if the trocar 130 comprises an outer sheath 133 (see Figure 15), the obturator portion of the trocar 130 can be withdrawn leaving the sheath 133 positioned through the access portal. An endoscope or other instrumentation can be inserted through the sheath 133 as shown in Figure 16. In this embodiment, the remaining sheath forms a lumen from exterior of the patient to the body cavity. Sheath 133 further provides the advantage of protecting the tissue surrounding the access portal from trauma as an endoscope or other instrumentation is advanced there-through to perform procedures within the body cavity. The sheath 133 also eliminates the need to dilate the access portal, which could damage the tissue surrounding the access portal to the body cavity.

[0068] Upon completion of the desired examination and/or treatment with the body cavity, the access portal is closed by ligating the suture portions 119 of the suture anchors 115. One method of ligating the sutures is by ensnaring (Figure 18) and withdrawing (Figures 19-20) the sutures through the main lumen of the overtube by using suture exchanger 151. More specifically, the sutures are unknotted or cut from the proximal end of over-tube 110. As illustrated in Figure 17, overtube 110 is then partly withdrawn from the patient, thereby exposing suture portion 119 at the distal end of overtube 110. Hook 157 of suture exchanger 151 can then ensare (Figure 18) and withdraw (Figures 19-20) suture portions 119 through main lumen 113. After the sutures are extracted through the main lumen, the physician can use conventional techniques to close the trocar puncture.

[0069] Figure 24 further illustrates this method of using suture exchanger 151. In step 163, the suture exchanger is passed through the main lumen of the over-tube. In step 165, the sutures are released from the proximal end of the overtube. In step 167, the overtube

is partly retracted and the suture exchanger hook is used to ensnare and withdraw the suture portions through the main lumen. In step 169, the physician ligates the sutures, thus closing the trocar puncture.

5 [0070] In an alternative ligating method, the suture portions of the suture anchors are pulled through a longitudinal slit 161 that extends along the length of attachment lumens 114. Longitudinal slit 161 extends from the attachment lumens into main lumen 113, as illustrated
10 in Figure 22, or alternatively, to the exterior of the over-tube, as illustrated in Figure 23. Instead of using a longitudinal slit, a splittable wall can be provided in the overtube. In either case, the suture portions are dislocated from the attachment lumens into either the main
15 lumen 113 or the exterior of overtube 110. This allows the physician to tie the suture portions and ligate the trocar puncture site with the suture portions of the suture anchors. Ligation can be accomplished with conventional ligating techniques, or as described below in greater
20 detail.

[0071] In another alternative ligating method illustrated in Figure 25, the overtube is entirely withdrawn from the patient before the trocar puncture is ligated. In particular, as described above, upon completion of the desired examination and/or treatment with the body cavity, the sheath is removed. In step 173 of Figure 25, the proximal ends of the suture portions are released from the overtube, thus detaching the overtube from the stomach wall. In step 175 the overtube is withdrawn
30 from the patient, thereby leaving the proximal ends of the suture portions extending from the patient's mouth. In step 177A, the physician uses an endoscope and a flexible endoscopic suturing device to approximate the tissue surrounding the puncture site. The physician can use a flexible Sew-Right® device, which is available
35 from Wilson-Cook Medical, Winston-Salem, NC. Alternatively, in step 177B the physician can endoscopically trim and ligate the suture portions with conventional ligating techniques.

40 [0072] As illustrated in Figure 10, the flexible trocar 130 comprises an obturator having a sharp, wedge tip 135. In one embodiment, the sharp, wedge tip 135 comprises beveled edges. Optionally, the flexible trocar 130 includes a sheath 133 (see Figure 11). Optionally, the
45 flexible trocar further includes a wire guide lumen 137 to accommodate a wire guide (not shown) that enables a guided puncture of the body wall.

[0073] Figure 26 illustrates an alternative safety trocar, and in particular, safety trocar 500. Safety trocar 500 includes a trocar tube 502 and obturator 515 inserted in trocar tube 502. Trocar tube 502 comprises dilator tip 501 located at the distal end of trocar tube 502 and protective outer sheath 506 disposed along an outer surface of trocar tube 502. Trocar tube 502 and dilator tip
50 501 can be formed from any suitable polymers known in the art, such as biocompatible polymers. Trocar tube 502 can also be provided with a PTFE coating. The coating can also comprise a hydrophilic polymer selected

from the group comprising polyacrylate, copolymers comprising acrylic acid, polymethacrylate, polyacrylamide, poly(vinyl alcohol), poly(ethylene oxide), poly(ethylene imine), carboxymethylcellulose, methylcellulose, poly(acrylamide sulphonic acid), polyacrylonitrile, poly(vinyl pyrrolidone), agar, dextran, dextrin, carrageenan, xanthan, and guar. The hydrophilic polymers can also include ionizable groups such as acid groups, e.g., carboxylic, sulphonic or nitric groups. The hydrophilic polymers may be cross-linked through a suitable cross-binding compound. The cross-binder actually-used depends on the polymer system: if the polymer system is polymerized as a free radical polymerization, a preferred cross-binder comprises 2 or 3 unsaturated double bonds.

[0074] Obturator 515 comprises an obturator tip 517 at the distal end of obturator 515, a handle 503 at the proximal end of obturator 515, and an elongated shaft 530 between the distal and proximal ends of obturator 515. Obturator tip 517 is biased toward a concealed position within dilator tip 501, as shown in Figures 26-27 and as described in greater detail below. When tissue is desired to be cut or penetrated, obturator tip 517 is extended distally through dilator tip 501 (see Figure 36). Since obturator tip 517 is biased toward a concealed position, immediately after the desired cut is made, obturator tip 517 automatically retracts within dilator tip 501.

[0075] Figure 30 illustrates a side view of obturator 515 having of a proximal handle 503, a distal obturator tip 517, and an elongated shaft 530 situated between the proximal and distal regions of obturator 515. Elongated shaft 530 can be manufactured from any relatively rigid, commercially available material, such as polymers or metals. Such materials should be axially strong enough to drive the obturator tip through tissue, while sufficiently flexible for endoscopic use. One such material is stainless steel, although many alternative materials will be apparent to one of ordinary skill in view of the present disclosure. As shown in Figure 30, handle 503 is attached to the proximal end of elongated shaft 530. Handle 503 is configured to be easily grasped by a physician's hand and is preferably T-shaped. Handle 503 also provides leverage for tissue incision, puncturing, and cutting.

[0076] Figure 27 illustrates a side view of dilator tip 501, with obturator tip 517 retracted and completely encased within dilator tip 501. Dilator tip 501 shields obturator tip 517, thereby preventing accidental or unintended puncture of tissue and internal organs while the obturator tip is not in use. Dilator tip 501 can be provided as a rounded, bullet-shaped housing that surrounds the entire outside of obturator tip 517 when obturator tip 517 is not in an extended position for cutting tissue. The surface of dilator tip 501 gradually tapers and ultimately converges at the distal end of dilator tip 501 where a longitudinal slot 504 is formed. Longitudinal slot 504 provides an orifice through which obturator tip 517 extends distally and can contact tissue.

[0077] In one embodiment, dilator tip 501 and trocar tube 502 can be constructed as an integral piece. Alternatively, dilator tip 501 can be a separately manufactured component, which is readily detached from trocar tube 502.

[0078] As Figure 26 illustrates, protective outer sheath 506 is a separate component, axially slidable relative to trocar tube 502. Sheath 506 includes an axial passageway 546 and a lubricious exterior wall 545. The axial passageway 546 is adapted to receive trocar tube 502. There is minimal clearance between the diameter of axial passageway 546 and the diameter of trocar tube 502 in order for trocar tube 502 and obturator 515 inserted therein to be securely positioned and aligned with the desired access portal 180 to the body cavity (see Figure 38). Surface wall 545 provides a smooth contact surface with the outer surface of trocar tube 502, thereby allowing trocar tube 502 to smoothly slide within axial passageway 546 of protective outer sheath 506.

[0079] Figure 28 shows an end-view of dilator tip 501. Longitudinal slot 504 allows the obturator tip 517 to extend distally from dilator tip 501 to penetrate and cut the desired tissue and thereafter retract proximally into dilator tip 501 when the required cutting has been performed. The longitudinal slot 504 corresponds to the geometry of the obturator tip 517.

[0080] As shown in Figure 27, the surface of dilator tip 501 is flush with trocar tube 502 outer surface so as to provide a smooth transition between trocar tube 502 and the tapered outer surface of dilator tip 501. The smooth transition ensures minimal trauma upon insertion of dilator tip 501 and trocar tube 502.

Additionally, the bullet-nose shape of dilator tip 501 can be used to further dilate the tissue after obturator tip 517 has made an initial incision. Moreover, dilator tip 501 is relatively wide, and thus provides a stable support or platform on which to cut tissue.

[0081] Figure 29 shows trocar tube 502 without obturator 515 inserted. Trocar tube 502 contains a lumen 507 through which obturator 515 is inserted and advanced therethrough until obturator tip 517 is completely encased within dilator tip 501. Clearance is preferably provided between the inside diameter of lumen 507 (Figure 29) and the outside diameter of elongated shaft 530 of obturator 515 (Figure 30). As a result, obturator 515 slides smoothly within trocar tube 502 during both extension and retraction of obturator tip 517.

[0082] Obturator tip 517 can consist of a variety of cutting edges, as shown in Figures 31-33. Figure 31 shows a double-edged obturator tip 517. In an alternative embodiment shown in Figure 32, tip 517 can be a flat, scalpel-like blade which allows for a clean incision, thereby minimizing tearing of surrounding tissue. As shown in Figure 33, obturator tip 517 can also consist of a serrated knife edge. The serrated knife edge produces greater surface area contact with the tissue which reduces the force required to cut the tissue. Obturator tip 517 can be formed from any malleable material that can be sharp-

ened. Examples of such materials include, but are not limited to, stainless steel and ceramics. Many alternative materials will be apparent to one of ordinary skill in view of the present disclosure.

[0083] Referring to Figure 38, after obturator 515 and trocar tube 502 are inserted into the main lumen 113 of overtube 110, obturator tip 517 is ready to be activated to extend distally and penetrate the desired body tissue. Activating obturator tip 517 to extend through longitudinal slot 504 (Figure 28) of dilator tip 501 can be achieved in numerous ways. Figure 26 shows a manual safety trocar 500, in which obturator tip 517 extends distally through longitudinal slot 504 of dilator tip 501 when manual force is applied at proximal handle 503. In such an embodiment, the force applied at proximal handle 503 is transmitted to elongated shaft 530 and, ultimately, to obturator tip 517.

[0084] Figure 34 depicts an obturator 532 with the proximal region of elongated shaft 530 having coiled springs 505. Figure 34 also shows corresponding trocar tube 531, into which obturator 532 is inserted. Trocar tube 531 contains flanges 511 located at the proximal end. Figure 35 shows obturator 532 fully inserted into lumen 507 of trocar tube 531. Figure 36 shows flanges 511 at the proximal end of obturator 532 engaging coiled springs 505. As obturator handle 503 is forced distally, flanges 511 compress coiled springs 505. In addition, obturator tip 517 extends distally through longitudinal slot 504 of dilator tip 501 and eventually punctures the desired tissue, as shown in Figure 36. The compressed spring coils 505 urge obturator 532 back into the retracted proximal position when they are not being pushed by the user. Spring coils 505 also provide stability to flexible obturator 532 such that a precise cut can be made.

[0085] The combination of a longitudinally slotted 504 dilator tip 501, corresponding to the geometry of obturator tip 517, and a coiled spring 505, wrapped around the proximal end of elongated shaft 530 of obturator 532, reinforce the blade to enhance cutting performance.

[0086] The safety trocar may also include a ratchet mechanism 549 to extend and retract obturator tip 517. Figure 37 shows a side view of obturator 533 with a ratchet mechanism 549. The ratchet mechanism 549 consists of a pivoting toothed cam 550, which engages matching teeth 529 on the proximal end of elongated shaft 530 of obturator 533. A spring 553 connected to the handle 503 of trocar tube 502 allows for extension of obturator tip 517 in small incremental distances through longitudinal slot 504 of dilator tip 501. Such a ratchet-like operation permits obturator 533 to incrementally extend to create the necessary tissue puncture while providing tactile feedback to the physician indicating that obturator 533 is being advanced through the tissue. The ratchet-mechanism also prevents the sudden release of back pressure associated with puncturing tissue thereby eliminating accidental extension of obturator tip 517 through tissue and organs. Other embodi-

ments for activating obturator tip 517 to extend and retract will become apparent to one of ordinary skill in the art in view of the present disclosure. Moreover, any of the above described safety trocars can be used in the procedure for accessing a body cavity, described below.

[0087] Because protective outer sheath 506 is axially slidable relative to trocar tube 502, after obturator tip 517 has created the desired access portal 180 to the body cavity, obturator 515 and trocar tube 502 can be withdrawn from protective outer sheath 506, as shown in Figure 38. Protective outer sheath 506 functions as an accessway to the body cavity. Because the tissue that lines stomach wall 8 is thick and tortuous, the trocar cut or puncture is typically not clean. The protective outer sheath 506 mitigates additional trauma incurred by passing the endoscope through the access port multiple times or from passing various accessories through the access port.

[0088] The above description is an exemplary application of safety trocar 500 to create an access portal to a body cavity. However, in view of the present disclosure, one of ordinary skill would know how to use the safety trocar 500 in a variety of other applications. For example, such a safety trocar can be used in colonoscopic or thoracic applications.

[0089] The above Figures and disclosure are intended to be illustrative and not exhaustive. This description will suggest many variations and alternatives to one of ordinary skill in the art. All such variations and alternatives are intended to be encompassed within the scope of the attached claims. Those familiar with the art may recognize other equivalents to the specific embodiments described herein which equivalents are also intended to be encompassed by the attached claims.

For example, the invention has been described in the context of accessing the peritoneal cavity for illustrative purposes only. Application of the principles of the invention to access other body cavities, such as the thoracic cavity, by way of a non-limiting example, are within the ordinary skill in the art and are intended to be encompassed within the scope of the attached claims. Moreover, in view of the present disclosure, a wide variety of safety trocars and suture exchangers will become apparent to one of ordinary skill in the art.

Claims

1. A device for accessing a body cavity through a body wall of a patient comprising:

a flexible, multi-lumen overtube comprising a distal end, a main lumen configured to receive an endoscope, and an outer lumen configured to receive an attachment mechanism, wherein the attachment mechanism is configured to secure the distal end of the multi-lumen overtube to the body wall.

2. The device of claim 1 further comprising a trocar tube configured to be disposed in the main lumen, the trocar tube comprising an elongate shaft and an obturator operably connected to the elongate shaft.
3. The device of claim 2, wherein the trocar further comprises a cutting portion and a sheath slidable relative to the obturator.
4. The device of one of claims 2 and 3, wherein the trocar tube further comprises an elongate shaft and a wire guide lumen extending axially through the shaft.
5. The device of any preceding claim comprising a suture exchanger, the suture exchanger comprising a shaft having an axial length larger than the axial length of the overtube, the shaft having a proximal portion and a hook portion located distal to the proximal portion, wherein the suture exchanger is configured to be inserted into the main lumen of the overtube.
6. The device of claim 5 wherein the shaft defines a longitudinal axis and the hook is offset from the longitudinal axis.
7. The device of any preceding claim wherein the outer lumen comprises a longitudinal slit extending along the length of the outer lumen.
8. The device of any preceding claim wherein the main lumen comprises a longitudinal slit extending along the length of the main lumen.
9. The device of any preceding claim wherein the attachment mechanism comprises a suture anchor having a filament and an anchor attached to the filament.
10. The device of claim 9 wherein the filament is configured to be pulled into the main lumen through the slit.
11. The device of any preceding claim wherein the flexible, multi-lumen overtube further comprises a valve at a proximal end to form a seal about the endoscope disposed within the main lumen.
12. A safety trocar comprising:
 - a shaft having an axial length between about 50 centimeters and about 100 centimeters, a distal end, a proximal end, and a lumen extending therebetween; and
 - an obturator disposed within the lumen of the trocar tube, the obturator having an axial length greater than the axial length of the trocar tube.
13. The safety trocar of claim 12, wherein the obturator further comprises:
 - a distal end, a proximal end, and a longitudinal portion therebetween;
 - an obturator tip positioned at the distal end of the obturator, wherein the obturator tip is slidable between a first position and a second position, wherein in the first position the distal tip is located distal to the trocar tube distal end, and in the second position, the distal tip is located proximal to the trocar tube distal end; and
 - a handle operably connected to the proximal end of the obturator.
14. The safety trocar of one of claims 12 and 13 wherein the trocar tube further comprises:
 - a protective sheath slidable relative to the trocar tube; and
 - a dilator tip operably connected to the distal end of the trocar tube.
15. The safety trocar of claim 13 wherein the obturator tip is configured to extend distal to the dilator tip in a first position and retract proximal to the dilator tip in a second position.
16. The safety trocar of claim 14 wherein the protective sheath is axially slidable relative to the trocar tube.
17. The safety trocar of one of claims 13 and 15 wherein the obturator tip includes a means for penetrating tissue.
18. The safety trocar of one of claims 13, 15, and 17 wherein the proximal end of the obturator further comprises a ratchet mechanism configured to ratchet between the first position and the second position.
19. A method for accessing a body cavity of a patient comprising the steps of:
 - (a) providing a flexible, multi-lumen overtube comprising a proximal end, a distal end, a main lumen and at least one attachment lumen;
 - (b) positioning an endoscope to extend through at least a portion of the main lumen;
 - (c) positioning at least one attachment mechanism to extend through at least a portion of the

at least one attachment lumen;

(d) positioning the flexible, multi-lumen over-
tube through a body orifice and along at least
a portion of a body passageway such that the
distal end is adjacent a selected portal sight
along a body wall;

(e) securing the distal end of the flexible, multi-
lumen overtube to the body wall at the selected
portal sight by advancing the at least one at-
tachment mechanism through the at least one
attachment lumen and into the body wall at the
selected portal sight;

(f) withdrawing the endoscope from the main lu-
men;

(g) advancing a trocar through the main lumen
and into the body wall to form a portal at the
selected portal sight;

(h) removing the trocar from the main lumen;

(i) advancing the endoscope through the main
lumen so that a distal end of the endoscope is
disposed adjacent or into the portal; and

(j) viewing at least a portion of the body cavity.

20. The method of claim 19 further comprising the step
of:

(k) closing the portal with the at least one at-
tachment mechanism.

21. The method of one of claims 19 and 20 wherein the
attachment mechanism comprises a suture anchor.

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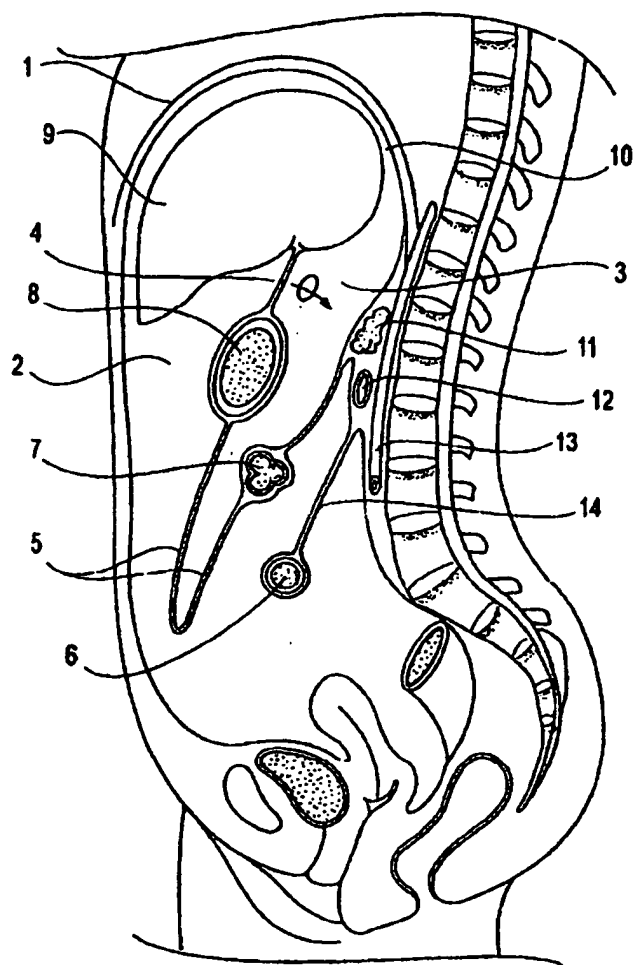


FIG. 1

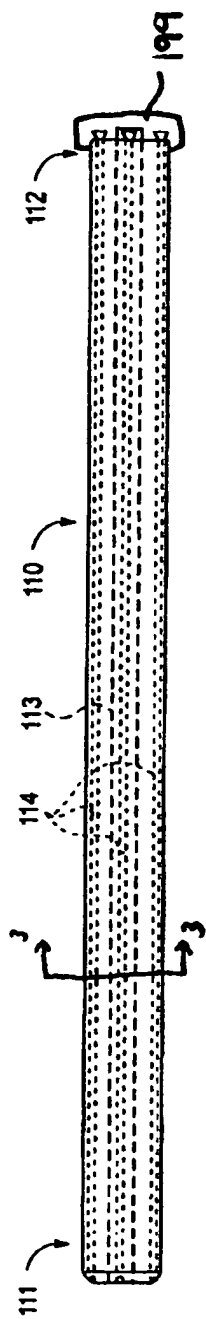


FIG. 2



FIG. 3



FIG. 4



FIG. 5

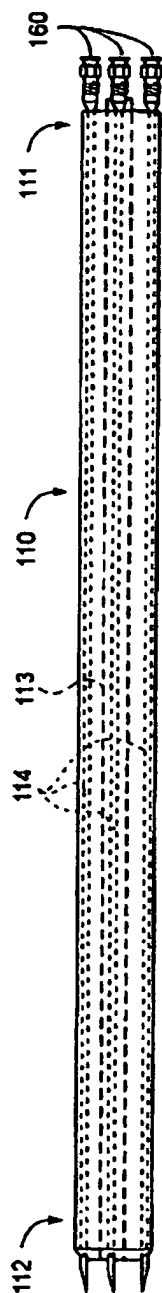


FIG. 6



FIG. 7



FIG. 8

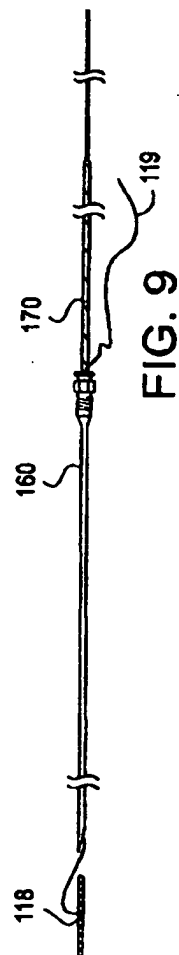


FIG. 9

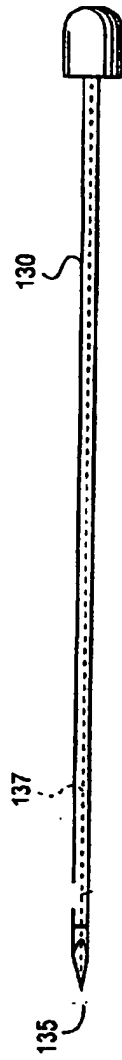


FIG. 10

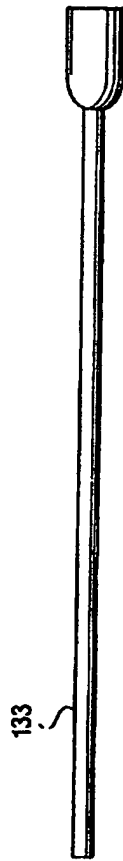


FIG. 11

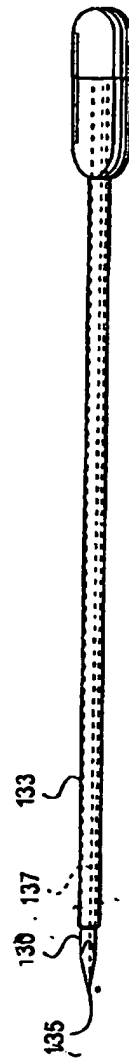


FIG. 12

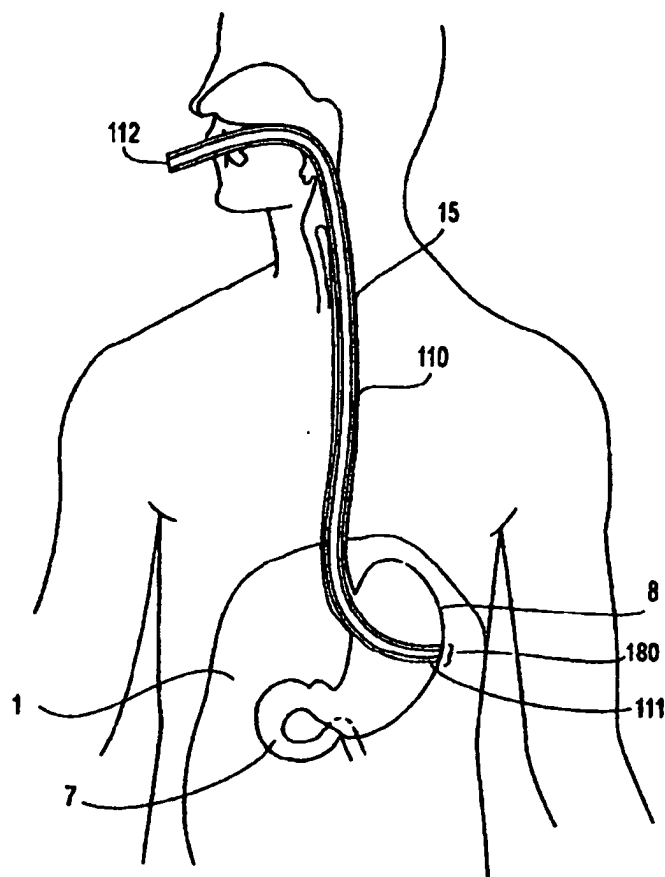


FIG. 13

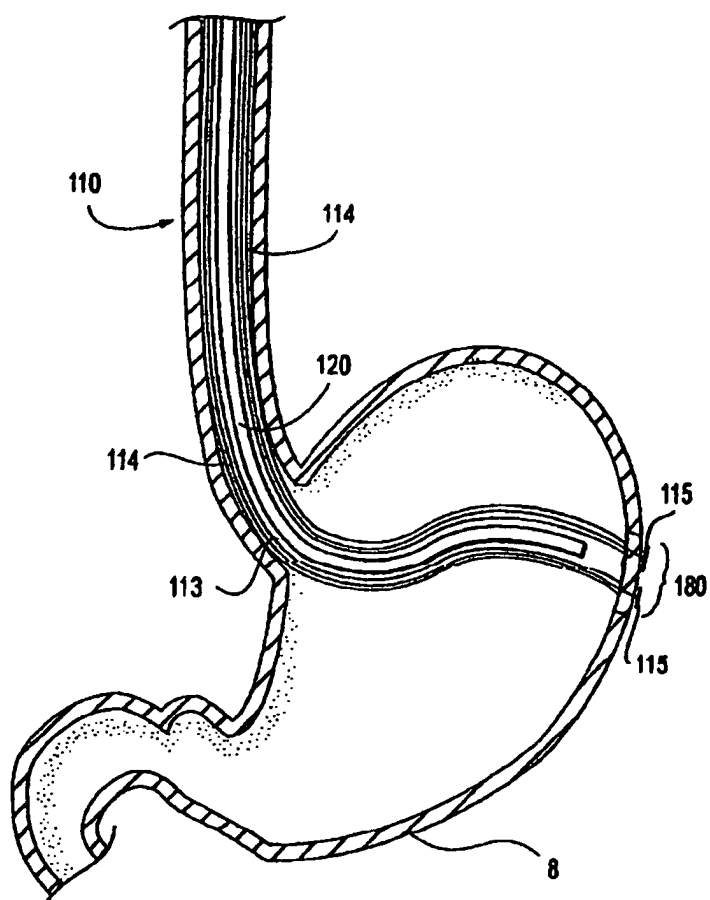


FIG. 14

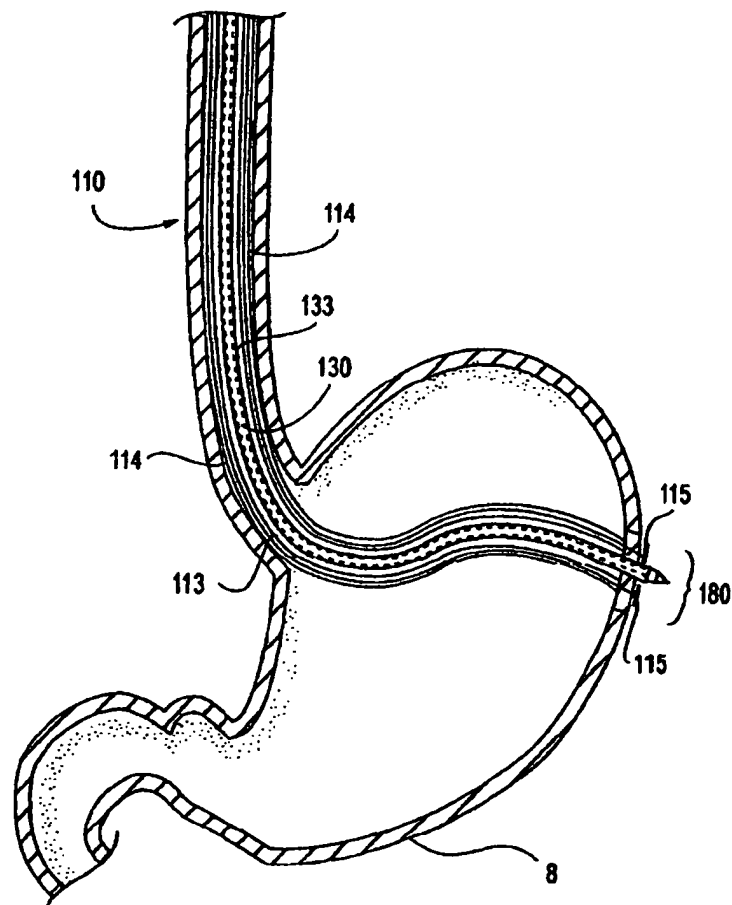


FIG. 15

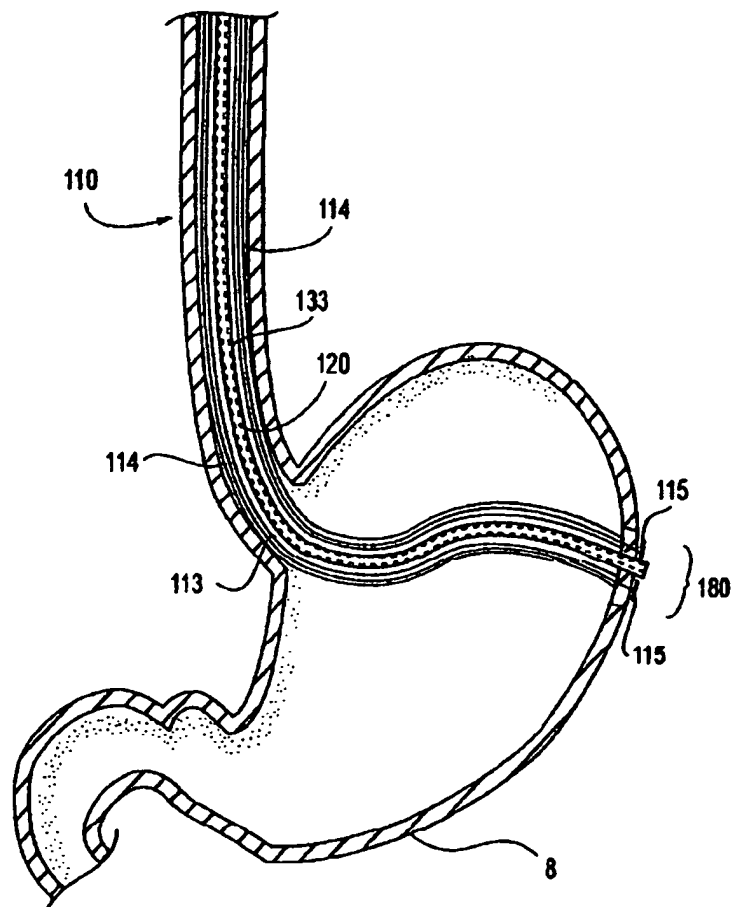


FIG. 16

Figure 17

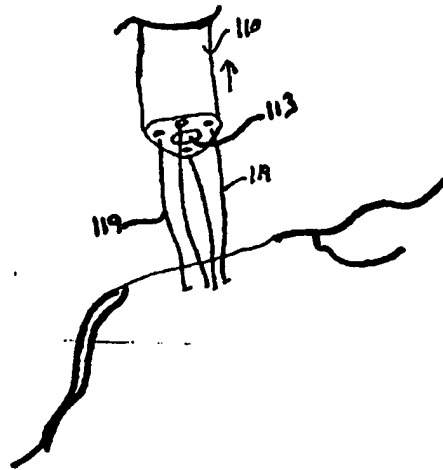


Figure 18

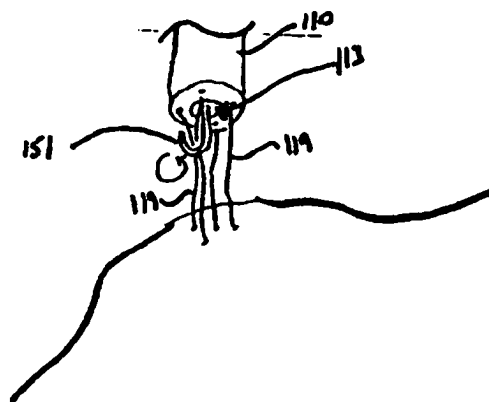
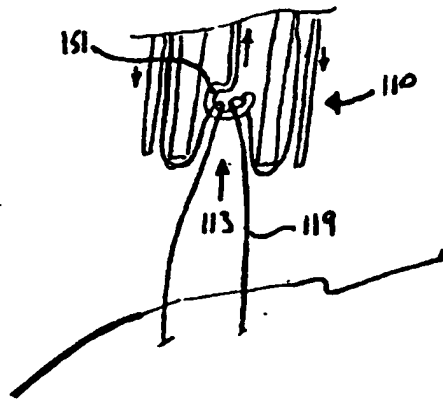


Figure 19



Figure 20



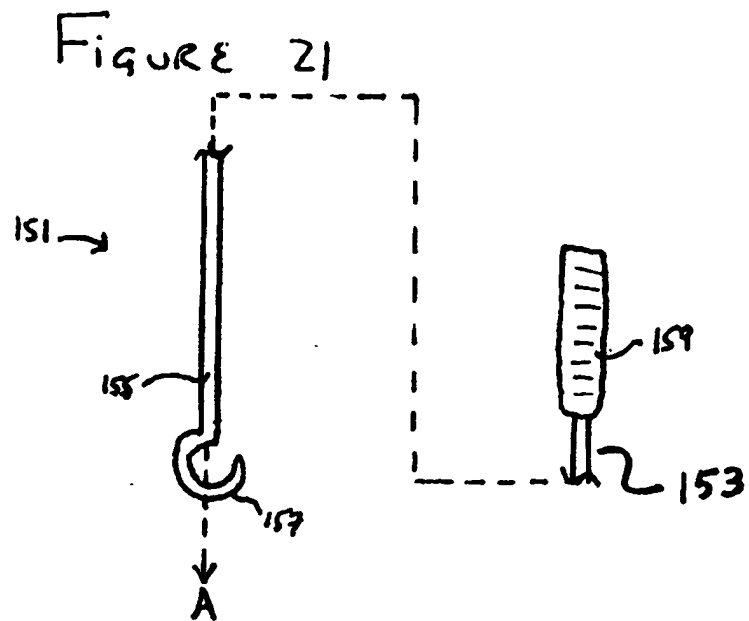
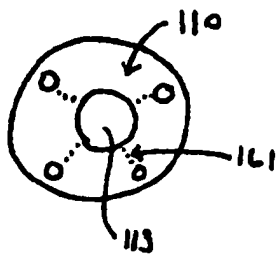


Figure 22



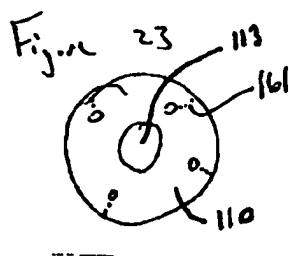


Figure 24

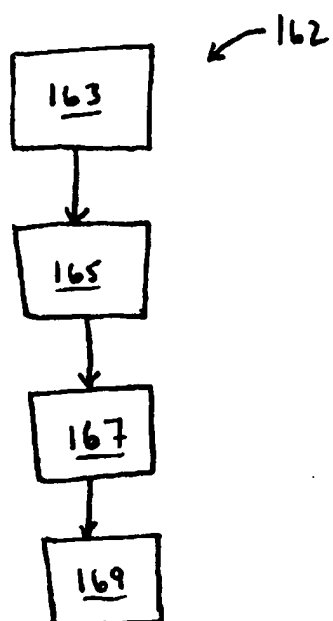


Figure 25

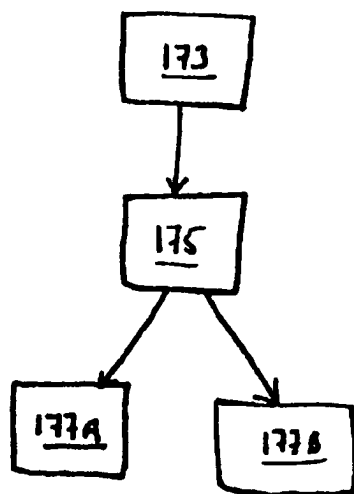


Figure 26

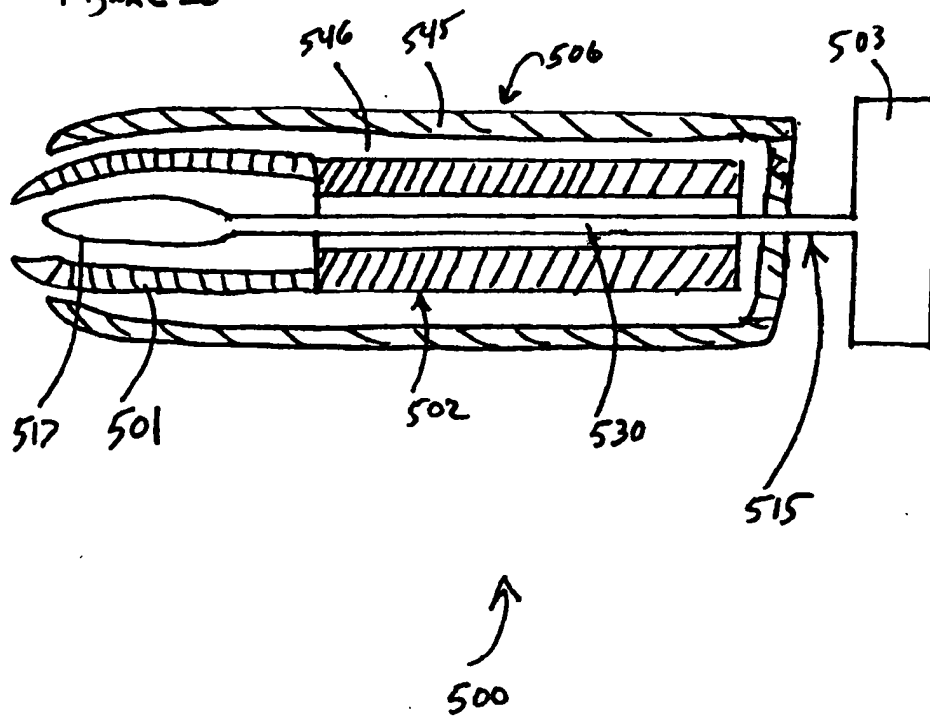


Figure 27

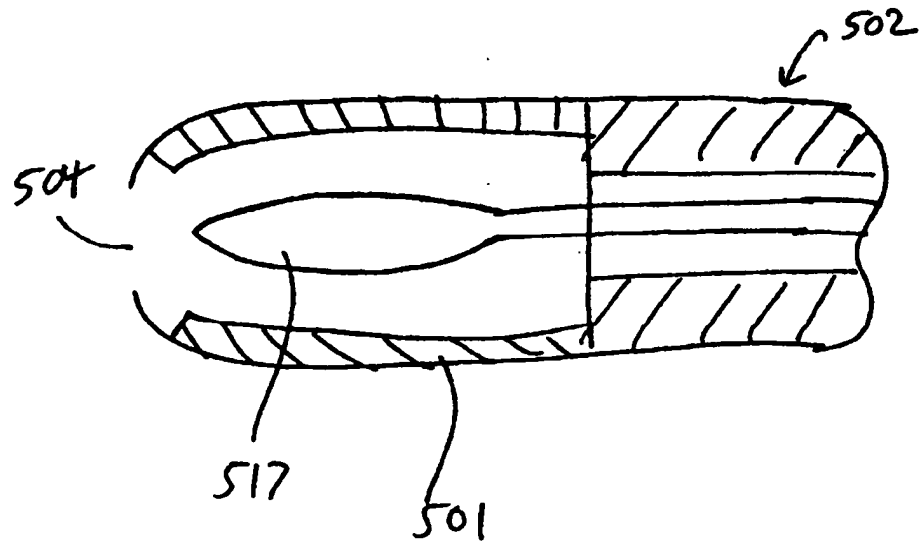


Figure 28

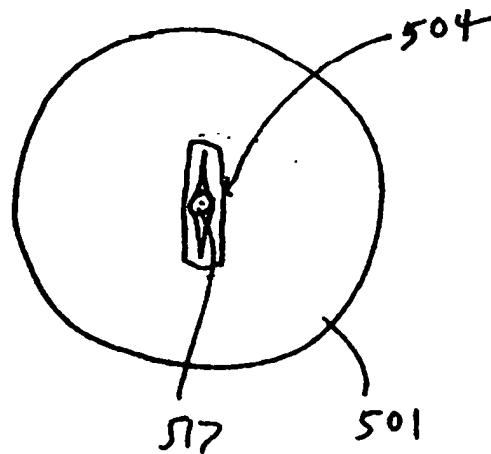


Figure 29

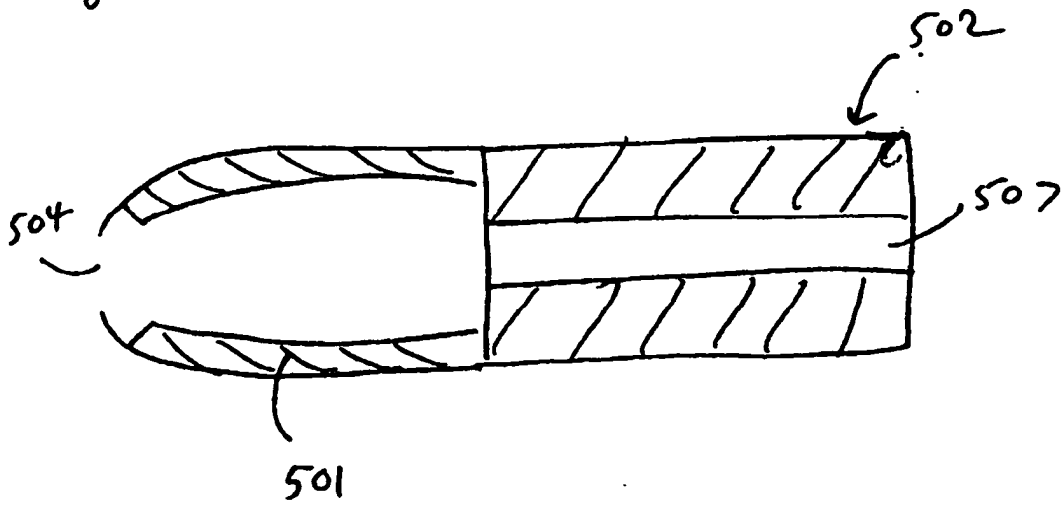


Figure 30

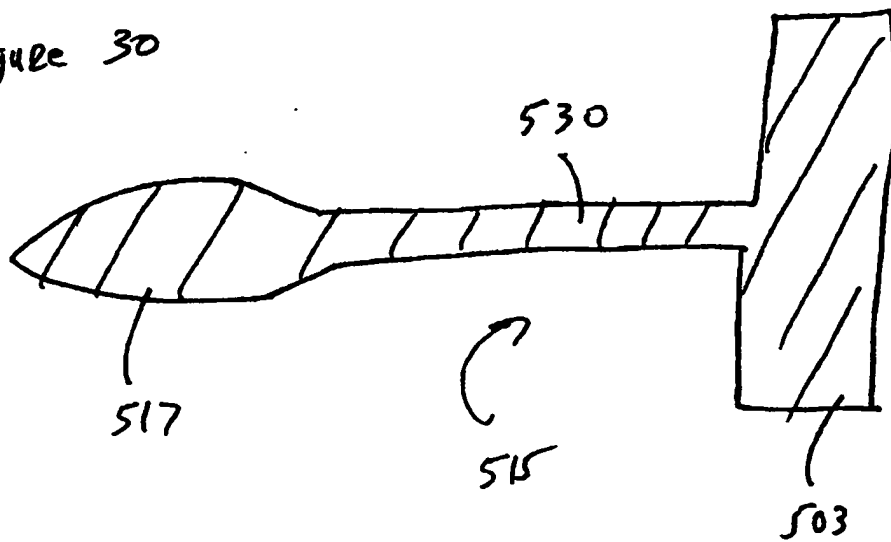


Figure 31

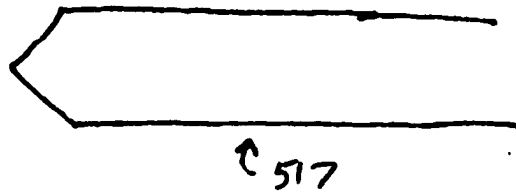


Figure 32

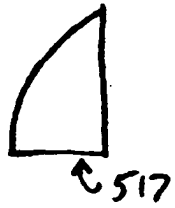


Figure 33

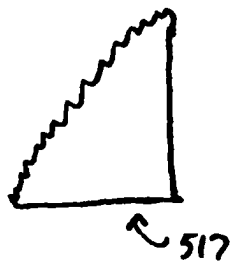


Figure 34

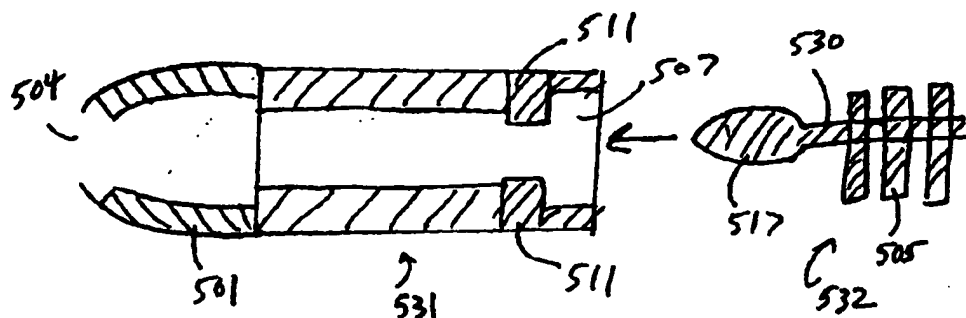


Figure 35

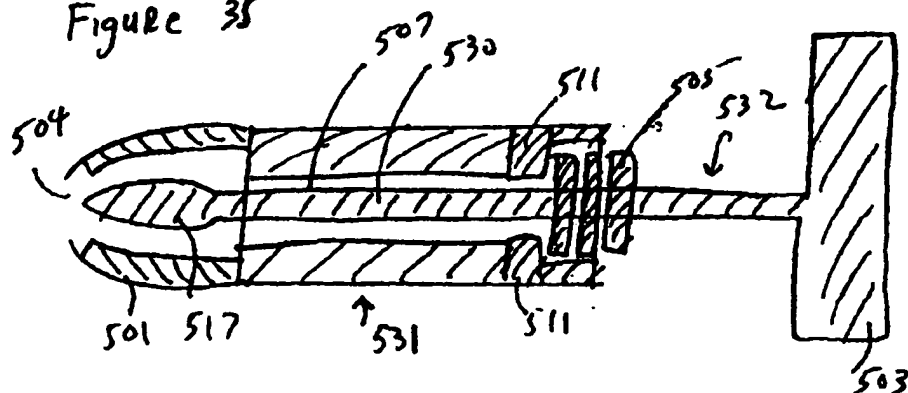


Figure 36

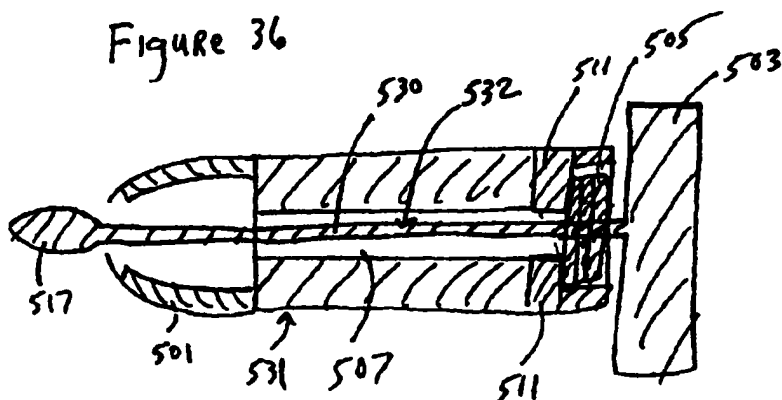


Figure 37

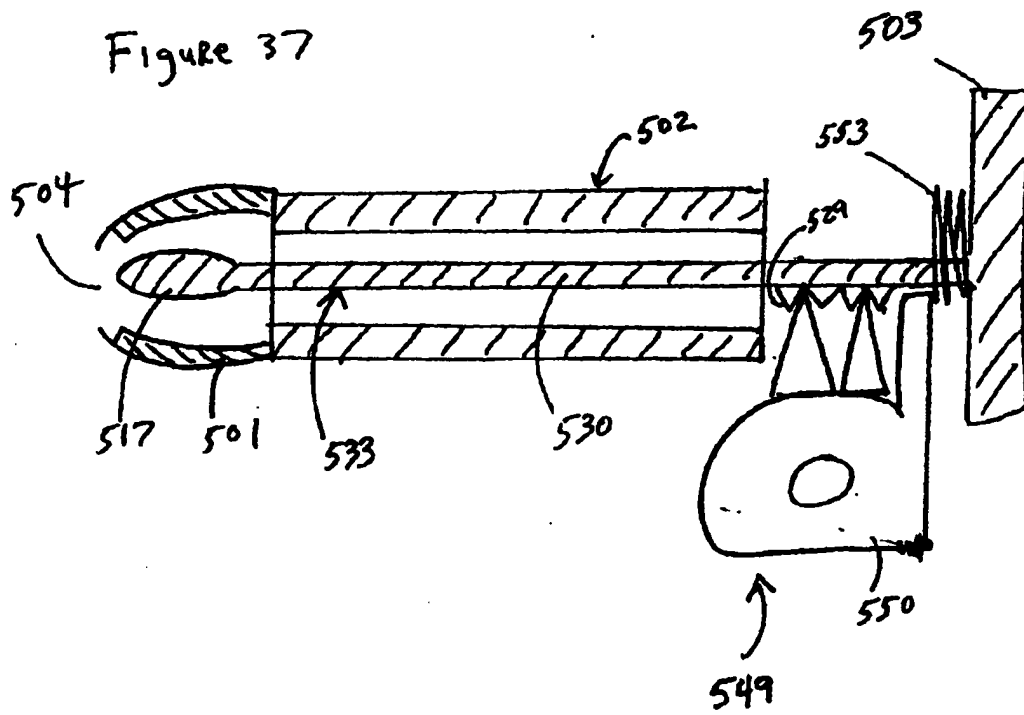


Figure 38

